

REMARKS

Claims 11-13, 16, 20-27, 32-34, 36, 44, 50-69, 71-81, and 83-99 are pending and under examination. Claims 13, 20, 21, 36, 55, 57, 71 and 72 have been canceled in order to reduce substantial overlap between claims based on previous amendments to the claims. Claims 67, 76, 78, 81 and 83 have been amended. New claims 100-109 have been added. Support for the amendments and new claims can be found throughout the specification and the claims as filed. In particular, support for new claims 100-109 can be found, for example, in Table 1 on page 33. Accordingly, these amendments and new claims do not raise an issue of new matter and entry thereof is respectfully requested.

Rejection Under 35 U.S.C. § 102

The rejection of claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, 67, 68, 71-73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. § 102(b) as allegedly anticipated by Turner et al., Breast Cancer Res. Treatment 46:69 (1997), is respectfully traversed. Applicant respectfully maintains, for the reasons of record, that Turner et al. does not anticipate the claimed methods.

The Office Action states on page 3 that:

Turner et al. determined the expression of BAG-1 in benign breast epithelium (BBE), ductal carcinoma in situ (DCIS), and invasive carcinoma (IC) of the breast in 87 breast cancer patients..., of which 82 patients have IC and 5 patients have pure DCIS... Turner et al. teach the slides were rated on a scale of intensity and % distribution within the BBE, DCIS and IC components... Turner et al. teach that the patients had a median follow-up of 13 years. Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC. The instant specification teaches that stage I of breast cancer requires no lymph node involvement, and stage II of breast cancer involves either no lymph node involvement and a large primary tumor or initial lymph node involvement and a small primary tumor... Because DCIS is a breast cancer with no lymph node involvement, the DCIS reads on the instant stage I, and stage II with no lymph node involvement. Therefore, Turner et al. teach all limitations of the claims.

With respect to the stages of breast cancer, Applicant maintains that DCIS is different from stage I breast cancer and stage II breast cancer. Applicant refers to Exhibit 1 previously submitted with the response filed December 13, 2006, which describes DCIS as a non-invasive type of breast cancer. As further evidence to clarify the nature of DCIS, submitted herewith as Exhibit 1 is a printout from the Breastcancer.org website entitled “Non-Invasive or Invasive Breast Cancer?” (www.breastcancer.org/symptoms/diagnosis/invasive.jsp). Additionally submitted herewith as Exhibit 2 is a printout from the Breastcancer.org website entitled “Stages of Breast Cancer” (www.breastcancer.org/symptoms/diagnosis/staging.jsp). DCIS, or ductal carcinoma *in situ* (“*in situ*” means “in the same place”), is described as a non-invasive breast cancer confined to ducts or lobules in the breast with no sign of spreading to the surrounding tissues (see page 1 of Exhibit 1). DCIS is considered stage 0 of breast cancer (see page 1 of Exhibit 2).

As indicated in Exhibit 2, unlike in DCIS, breast cancer at stage I or stage II is considered to be invasive. Stage I has no lymph node involvement, whereas stage II can have a tumor of a given size without lymph node involvement or can have lymph node involvement (see specification on page 25, lines 10-22, and Exhibit 2). Stage III and stage IV are also invasive breast cancers, staged based on tumor size, lymph node involvement and metastasis (see Exhibit 2). Additional details and characteristics of the stages of breast cancer are provided in Exhibit 3, which is pages 35-37 of Markman, Basic Cancer Medicine (1997), as referenced in the specification on page 25, lines 12-22. According to the tumor-node-metastasis (TNM) staging system, there are thirteen distinguishable TNM stage groupings within stage I to stage IV of breast cancer (see page 36 of Exhibit 3).

In contrast to the claimed methods, which recite stage I and stage II breast cancer, Turner et al. provides no teaching of the stage of the breast cancer samples. Turner et al. is silent as to whether the breast samples were stage I, II, III or IV or any of the thirteen TNM stage groupings. According to MPEP § 2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. As discussed above, Turner et al. does not teach each and every element of the claims and thus fails to anticipate the claimed methods. In particular, Turner et al. provides no teaching of the claimed methods in which the breast cancers are stage I or stage II, with or without lymph node involvement. Absent such a teaching, Applicant respectfully submits that Turner et al. cannot

anticipate the claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 103

The rejection of claims 11-13, 16, 20-22, 24-27, 32-34, 36, 44, 50-61, 67-69, 71-73, 75-81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. § 103 as allegedly obvious over Turner et al., *supra*, in view of Sano et al., U.S. Patent No. 5,665,539, is respectfully traversed. Applicant respectfully maintains, for the reasons of record, that the claimed methods are unobvious over Turner et al., alone or in combination with Sano et al.

As discussed above, Turner et al. neither teaches nor suggests the claimed methods relating to stage I or stage II of breast cancer. Sano et al. does not cure this defect either, as it contains no teaching or suggestions that would complement the teaching of Turner et al. with regard to stage I or stage II of breast cancer. Therefore, Applicant respectfully maintains that the claimed methods are unobvious over Turner et al., alone or in combination with Sano et al. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

The rejection of claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-68, 71-73, 75-79, 81, 83-99 under 35 U.S.C. § 103 as allegedly obvious over Turner et al., *supra*, in view of Sauter et al., Br. J. Cancer 76:494-501 (1997), is respectfully traversed. Applicant respectfully maintains, for the reasons of record, that the claimed methods are unobvious over Turner et al., alone or in combination with Sauter et al.

As discussed above, Applicant respectfully maintains that Turner et al. does not teach or suggest the claimed methods relating to stage I and stage II of breast cancer. Furthermore, Applicant respectfully maintains that Sauter et al. does not cure the deficiencies of Turner et al. in teaching stage I and stage of breast cancer. Therefore, Applicant respectfully maintains that the claimed methods are unobvious over Turner et al., alone or in combination with Sauter et al. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

The rejection of claims 11, 13, 16, 20-27, 32, 34, 36, 44, 50-61, 67, 68, 71-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. § 103 as allegedly obvious over Turner et al., *supra*, in view of Takayama et al., Cancer Res. 58:3116-3131 (1998), is respectfully traversed.

Applicant respectfully maintains, for the reasons of record, that the claimed methods are unobvious over Turner et al., alone or in combination with Takayama et al.

As discussed above, Applicant respectfully maintains that Turner et al. does not teach or suggest the claimed methods relating to stage I and stage II of breast cancer. Furthermore, Applicant respectfully maintains that Takayama et al. does not cure the deficiencies of Turner et al. in teaching stage I and stage II of breast cancer. Therefore, Applicant respectfully maintains that the claimed methods are unobvious over Turner et al., alone or in combination with Takayama et al. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

The rejection of claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-68, 71-73, 75-79, 81, 83-99 under 35 U.S.C. § 103 as allegedly obvious over Turner et al., *supra*, in view of Love, U.S. Patent No. 6,221,622, is respectfully traversed. Applicant respectfully maintains, for the reasons of record, that the claimed methods are unobvious over Turner et al., alone or in combination with Love.

As discussed above, Applicant respectfully maintains that Turner et al. does not teach or suggest the claimed methods relating to stage I and stage II of breast cancer. Furthermore, Applicant respectfully maintains that Love does not cure the deficiencies of Turner et al. in teaching stage I and stage II of breast cancer. Therefore, Applicant respectfully maintains that the claimed methods are unobvious over Turner et al., alone or in combination with Love. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

Application No.: 09/350,518

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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